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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,933	03/08/2006	Roland Callens	05129-00120-US	8950
23416 7590 09/21/2007 CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207 WILMINGTON, DE 19899			EXAMINER PUTTLITZ, KARL J	
			ART UNIT 1621	PAPER NUMBER
			MAIL DATE 09/21/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/570,933	<b>Applicant(s)</b> CALLENS ET AL.	
	<b>Examiner</b> Karl J. Puttlitz	<b>Art Unit</b> 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 22-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

KARL PUTTLITZ  
PATENT EXAMINER

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/8/2006</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Objections***

Claim 22 is objected to because of the following informalities: "in which reagent at least one amino group of the amino acid . . .". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22, 26 and 27 recite a reagent based on enantiopure amino acid. It is unclear what compounds are intended by the term "based on".

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,097,490 to Reinhold (Reinhold).

The rejected claims cover, inter alia, a process for the manufacture of an enantiopure compound comprising at least one functional group capable of reacting with an activated carboxyl group, starting from a mixture of enantiomers of the said compound, in which process (a) a reaction medium comprising the mixture of enantiomers and a reagent based on an enantiopure amino acid, in which reagent at least one amino group of the amino acid is protected by a protective group and in which reagent at least one carboxyl group of the amino acid is activated, is subjected to conditions appropriate for bringing about the reaction of the functional group capable of reacting with the activated carboxyl group with the activated carboxyl group, so as to form a carbonyl bond; (b) the mixture of diastereomers obtained is subjected to a separation operation, so as to obtain at least one fraction composed essentially of a diastereomer; (c) at least a portion of the said fraction is subjected to a stage of cleavage of the carbonyl bond under conditions under which the protective group is essentially stable; and (d) the enantiopure compound and an enantiopure derivative of the amino acid in which at least one amino group is protected by the protective group are recovered.

The regard to the Above embodiments, Reinhold teaches a process for resolving mixtures of enantiomers of 1-t-butylamino-2,3-dihydroxypropane which comprises treating a solution of said mixture in a suitable solvent with an agent selected from S-pyroglutamic acid, R-pyroglutamic acid, L-(+)-tartaric acid and D-(-)-tartaric acid, separating, from the solution, solid diastereoisomer which forms and recovering from

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said diastereoisomer a single enantiomer of 1-t-butylamino-2,3-dihydroxypropane. See column 1, lines 55+.

Reinhold also teaches that the single enantiomer of 1-t-butylamino-2,3-dihydroxypropane is recovered from the separated diastereoisomer by conventional techniques. For example, the S-pyroglutamic acid.S-t-butylamino-2,3-dihydroxypropane diastereoisomer can be treated with a suitable base whereby the S-1-t-butylamino-2,3-dihydroxypropane is freed from the S-pyroglutamic acid. The S-1-t-butylamino-2,3-dihydroxypropane can then be recovered by extraction with a suitable solvent and the solvent stripped to yield the desired S-1-t-butylamino-2,3-dihydroxypropane. The neutralized S-pyroglutamic acid can be conventionally recovered from the remaining solution for re-use as a resolving agent. Another procedure for recovering the amine enantiomer from the separated diastereoisomer is to run a solution of the diastereoisomer through a suitable ion exchange resin column and then elute the free 1-t-butylamino-2,3-dihydroxypropane enantiomer. See description bridging columns 2 and 3.

The difference between the process set forth in the rejected claims and the process disclosed by Reinhold is that Rein hold fails to explicitly teach some of the specific amino protecting groups recited in the claims. However, it would havbe been obvious to substitute the S-pyroglutamic acid, R-pyroglutamic acid, L-(+)-tartaric acid and D-(-)-tartaric acid of the reference with the protected amino counterparts in order to obtain the predictable result of an enantiopure compound.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl J. Puttlitz whose telephone number is (571) 272-0645. The examiner can normally be reached on Monday to Friday from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at telephone number (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
KARL PUTTLITZ  
PATENT EXAMINER  
4/11/2007